DEPARTMENT OF HEALTH & HUMAN SERVICES

9-12-41d

Food and Drug Administration
Rockville MD 20857

February 9, 2001

CBER-01-013

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Samuel K. Ackerman, M.D.
President and CEO
CoPharma, Inc.
97 South Street
Hopkinton, MA 01748

Dear Dr. Ackerman:

The Food and Drug Administration has completed its review of the inspection of your manufacturing facility, Marathon Biopharmaceuticals, located at 97 South Street, Hopkinton, Massachusetts, between September 19-29, 2000. The inspection revealed significant deviations from current good manufacturing practice regulations (CGMP) in the manufacture of bulk denileukin diftitox. These violations of the CGMPs render the product adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Significant deviations observed during the inspection include, but are not limited to:

LABORATORY CONTROLS

1. There is no assurance that laboratory determination of satisfactory conformance to final specifications for a bulk drug substance was adequate. [redacted] bulk lot 28699HP did not meet release specifications for [redacted] levels. The lot was released and distributed.

2. There is no assurance that laboratory controls, including specifications, sampling plans, and test procedures are designed to assure that components, in-process materials, and bulk drug substance conform to appropriate standards. For example:

   a) During testing for [redacted] testing is not performed on the [redacted] mixture.

If you have any questions regarding this letter, please contact Ms. Mary A. Malarkey, Director, Division of Case Management, at (301) 827-6201.

Sincerely,

Deborah D. Ralston
Director
Office of Regional Operations

cc:

[redacted]